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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
09/234,733

Applicant(s)
Jiang et al

Examiner
Li Lee

Group Art Unit
1645



X Responsive to communication(s) filed on Dec 13, 1999

X This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- X Claim(s) 1-12 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- X Claim(s) 1-12 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s) PTO-1449, Paper No(s) _____

PTO-413

SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's amendment filed on Dec 13, 1999 (Paper Number 8) has been received and entered. Claims 1-6 have been amended, consequently claims 1-12 are pending in the instant application.

Rejections Withdrawn

2. The rejection of claims 2-3 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of Applicant's amendment.

4. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Williams et al. (Lett Appl Microbiol 12(1):23-8, 1991) is withdrawn in view of Applicant's amendment.

Rejections Maintained

3. The rejection of claims 2-3, 5-6, 8-9, and 11-12 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2, *Streptococcus uberis* CAMP factor, does not reasonably provide enablement for any variant of a isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 is maintained for reasons made of record in Paper No 5, mailed 08 17 99.

Applicant's are asserting that the claimed nucleic acid only encompasses to encode a

However, the specification fails to provide any evidence to support the claim that the claimed

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polypeptide variants of the SEQ ID NO:2. Since any five amino acids in length would form an immunogenic epitope, without specifically recitation of an epitope, one skilled in the art would be required to perform undue experimentation to identify any immunogenic activity that would be associated with a fragment or variants of SEQ ID NO:2. It is noted that the features upon which applicant relies (i.e., linear epitopes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant amended the claims to recite the 90% identity to the amino acid sequence of SEQ ID NO:2. Since the specification does not provide any guidance how to compare the claimed sequence to the vast number known nucleic acid sequences, one skilled in the art would be required to perform undue experimentation by using any set of DNA comparison parameters to identify any immunogenic activity that would be associated with a fragment or variants of SEQ ID NO:2.

Amendment of claims to clearly identify the biological activity of the fragment and the variant (e.g., a sequence encoding an amino acid sequence having same immunogenic activity of the amino acids sequence of SEQ ID NO:2) would obviate this rejection.

4. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Podblielski (Med Microbiol Immunol 183:239-256, 1994) is maintained for reasons made of record in Paper No 5, mailed 08/17/99.

not distinguish over the art of Podblielski. Podblielski teaches that a polypeptide sequence of 10-15 amino acids is sufficient to elicit an immune response.

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of the *cf6* gene encoding a immunogenic group B *Streptococcus* CAMP factor amino acid sequence having at least 10 contiguous amino acids 100 % identical to the sequence of SEQ ID NO:2 (see the sequence search from database SPTREMBL, result 2, attached to the office action).

5. The rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Podblielski (Med Microbiol Immunol 183:239-256, 1994) applied to claims 1-3 and Sambrook et al. (Molecular Cloning, A Laboratory Manual CSH 1989, 17 Expression of Cloned Genes in *Escherichia coli*) is maintained for reasons made of record in Paper No 5, mailed 08/17/99.

Applicants' amendments are insufficient to obviate this rejection because the claims do not distinguish over the art of Podblielski. Since the rejection under 102 do not fail, neither does the 103 based on these references.

Status of Claims

6. No claims are allowed. All claims stand rejected.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. To avoid a first reply being filed within TWO

months, an applicant must file a reply within the shortened statutory period. The shortened statutory period will expire on the date the advisory action is mailed, and any extension fee paid must be filed before the expiration of the shortened statutory period.

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee, M.D., Ph.D.

February 25, 2000


ANTHONY CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600